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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/812,704

Applicant(s)

LEWIS ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37, 39-46 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37, 39-46, and 51-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Amendment***

1. In the amendment filed 6/16/06, the following has occurred: no claims have been added, canceled, nor amended. Now, claims 1-37, 39-46, and 51-56 are presented for examination.
2. In addition, as noted in the response, the Declaration, filed 11/19/04 is sufficient to predate the Potter reference. Therefore, the Examiner withdraws this reference as a basis for rejection.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. Claims 1-37, 39-46, and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snail, **The Effects of Hospital Contracting for Physician Services on Hospital Performance** in view of Leet, U.S. Patent No. 6,000,828.
5. As per claim 1, Snail discloses a method of managing a healthcare practice participating in an insurance network to enhance profitability of the healthcare practice with respect to a predetermined reimbursement amount for pharmacy costs, the method comprising: gathering data for each of a plurality of physicians in the healthcare practice participating in the insurance network regarding management of the pharmacy costs other than those attributed by a medical procedure performed directly by each of the plurality of physicians when the physician directly administers a medication to a patient to thereby define ancillary pharmacy costs (see page 156, in particular, the statistical profiles used to compare physician practices); identifying at least one of the plurality of physicians in the healthcare practice participating in the insurance network

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that is at a greater risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network by prescribing medications that are detrimental to receiving the predetermined reimbursement amount for the ancillary pharmacy costs (see pages 156 and 161, in addition to identifying physicians by comparing individuals to other peer physicians, it is noted that incentive payments are disclosed as being based on costs, therefore, identified physicians would at least be at risk of not receiving the potential full amount of incentive payments identified in Snail); and after the step of identifying, modifying management behavior of the at least one of the plurality of physicians at the greater risk regarding the ancillary pharmacy costs to substantially reduce the risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network and thereby increase the profitability of the healthcare practice (see pages 162-163, it is noted that education is one of the disclosed methods of modification of physician behavior).

6. Snail does not explicitly disclose a tangible computer medium for gathering the data regarding the physicians. However, gathering data in a tangible computer medium is old and well known in the art as taught by Leet in which data regarding medical cost information is gathered in a tangible computer medium (see column 15, lines 11-28). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a computer tangible medium into the system of Snail. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of reducing the amount of paper records needed in Snail by automating the data collection process. In addition, such automation of such a process would aid in overcoming the difficulty in monitoring physician practice identified in Snail (see page 162).

7. As per claim 2, Snail in view of Leet discloses the method of claim 1 as described above. Snail does not explicitly teach that the ancillary pharmacy costs are gathered from a database

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associated with a pharmacy network, positioned on a server. Leet teaches gathering data regarding pharmacy costs from a database associated with a pharmacy network, the database positioned on a server (see column 18, line 49 – column 19, line 13 and column 5, line 65 – column 6, line 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the method of Snail for the reasons given above with respect to claim 1.

8. As per claim 3, Snail in view of Leet disclose the method of claim 1 as described above. Snail further discloses analyzing the ancillary pharmacy costs of each of the plurality of physicians in the healthcare practice to compare statistical profiles of physicians to one another (see page 156). However, Snail does not explicitly disclose calculating an average ancillary pharmacy cost per physician for the healthcare practice, and identifying the physicians that have ancillary pharmacy costs that are a predetermined percentage greater than the average ancillary pharmacy costs per physician for the healthcare practice. However, the Examiner takes Official Notice that it is old and well known in the art of statistical profiling to calculate averages and identify entities that are a predetermined percentage greater than the average. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a statistical analysis into the combined teachings of Snail and Leet. One of ordinary skill in the art would have been motivated to incorporate such a teaching for the purpose of evaluating performance to structure managed care contracts (see page 156 of Snail).

9. As per claim 4, Snail in view of Leet discloses the method of claim 1 as described above. Snail further discloses selecting the physician having the highest ancillary pharmacy costs within the healthcare practice (see page 156).

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10. As per claim 5, Snail in view of Leet discloses the method of claim 1 as described above. Snail further discloses modifying physician behavior through education (see page 163). However, Snail does not explicitly disclose modifying by educating the at least one physician on the benefits of alternative prescription medications using research literature for comparing the alternative medications to the prescribed medication and organizing continued medical education classes to educate each of the plurality of physicians in the healthcare practice on the benefits of the alternative prescription medications. However, Leet teaches such education by providing information regarding alternative prescription medications that can be ranked both by effectiveness and by cost (see column 14, lines 8-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the method of Snail. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of providing enhanced services to physicians based on the constantly evolving nature of medical knowledge (see column 11, lines 48-51 of Leet).

11. As per claim 6, Snail in view of Leet discloses the method of claim 5 as described above. Although Snail describes treatment-based guidelines for receiving the reimbursement amount, the reference does not explicitly teach preparing a list of prescription medications that the at least one physician may prescribe that enable the physician to receive the predetermined reimbursement amount for the ancillary pharmacy costs. However, Leet teaches presenting a list of prescription medications to physicians that the physician may prescribe based in part on cost (see column 14, lines 19-30) for the purpose of reducing healthcare costs (see column 1, lines 5-11). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the method of Snail. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of reducing healthcare

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costs without sacrificing the quality of health care provided to patients (see column 1, lines 5-11 of Leet).

12. As per claim 7, Snail in view of Leet disclose the method of claim 6 as described above. As described above, Snail does not explicitly disclose providing the alternative medications. However, Leet further teaches providing customer prescription medication forms that include the list of prescription medications that the at least one physician may prescribe (see Table III). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Snail for the reasons given above with respect to claim 6.

13. As per claim 8, Snail in view of Leet disclose the method of claim 7 as described above. Snail further discloses modifying physician behavior by utilizing payment incentive mechanisms based on the use of treatment protocols (see page 162 and Table A2.3). Snail does not explicitly disclose preparing a list of common prescription medications that are approved by each of the plurality of insurance networks so as to enable the at least one physician to receive the predetermined reimbursement amount for the ancillary pharmacy costs. However, Leet teaches preparing a list of suggested medications and corresponding costs (see column 25-29 and Table III). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize such a list as taught by Leet in conjunction with the use of treatment protocols. One of ordinary skill in the art would have been motivated to utilize such a list for the purpose of aiding in reducing unnecessary or inappropriate utilization (see page 162 of Snail).

14. As per claim 9, Snail in view of Leet disclose the method of claim 7 as described above. Snail does not explicitly teach analyzing the patient's prescription history to thereby avoid possible adverse prescription medication reactions. However, Leet teaches analyzing the patient's prescription history to thereby avoid possible adverse prescription medication reactions

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(see column 18, lines 57-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Snail for the reasons given above with respect to claim 6.

15. As per claim 10, Snail in view of Leet disclose the method of claim 9 as described above. Snail further discloses utilizing payment incentive mechanisms based on a review of the appropriateness of treatment prescribed by physicians (see page 162 and Table A2.3).

However, Snail does not explicitly disclose discontinuing the at least one patient's present prescription medications based on the review. Leet teaches discontinuing at least one patient's present prescription medications that have inadequate clinical effect (see column 19, lines 30-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Snail for the reasons given above with respect to claim 6.

16. As per claim 11, Snail in view of Leet disclose the method of claim 10 as described above. As noted above, Snail does not explicitly teach discontinuing the patients present medication, however, this is old and well known as evidenced by Leet above incorporated herein. In addition, neither Snail nor Leet explicitly teach the use of a physician's letterhead for communicating notification of discontinuing a prescription medication. The Examiner takes Official Notice that physician's letterhead used for physician communications such as discontinuing medications is old and well known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the use of physician's letterhead into the combined teachings of Snail and Leet. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of providing a professional means for communication with patients and pharmacies.



17. As per claim 12, Snail in view of Leet disclose the method of claim 1 as described above. Snail further discloses updating each of the plurality of physicians in the healthcare practice of any changes in the management of ancillary pharmacy costs from the insurance network (see page 156, in particular, physician profiles that are compared to practice guidelines are disseminated to physicians).

18. Claims 13-23 recite substantially similar limitations to those already addressed in claims 1-12 and, as such, are rejected for similar reasons as given above.

19. As per claim 24, Snail in view of Leet teach the method of claim 20 as described above. Snail further teaches the ancillary medical costs include any costs taken from the listed group (see pages 156 and 161).

20. Claim 25 recites substantially similar limitations to claim 13 with the additional limitation of providing a financial incentive to the insurance network and the plurality of physicians in the healthcare practice participating in the insurance network to modify the plurality of physicians' management behavior of ancillary medical costs that are not as profitable to the insurance network which is also taught by Snail (see pages 156 and 161). Claims 26-36 recite substantially similar additional limitations to those already addressed in claims 12-24 and, as such, are rejected for similar reasons as given above.

21. Claims 37, 39-46, and 51-56 recite substantially similar system limitations to those already addressed in method claims 12-24 and, as such, are rejected for similar reasons as given above.

### ***Response to Arguments***

22. In the remarks filed 6/16/06, Applicants argue in substance that the Declaration, filed 11/19/04, is sufficient to predate the Potter reference. The Examiner agrees and, accordingly,

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has withdrawn the reference as a basis for rejection. However, a new grounds of rejection in view of Snail, with a publication date prior to October 2000, have been detailed above.

### ***Conclusion***

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Rosenstein et al. discloses risk sharing strategies to change physician behavior, whereby physician compensation is tied to treatment costs.
- Cherney discloses various types of risk sharing strategies.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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8/17/06



C. LUKE GILLIGAN  
PATENT EXAMINER